

### PROPOSED RULE MAKING

# CR-102 (June 2004) (Implements RCW 34.05.320)

Agency: Department of Health	Do NOT use for expedited rule making
<ul> <li>✓ Preproposal Statement of Inquiry was filed as WSR <u>04-15-150</u></li> <li>✓ Expedited Rule MakingProposed notice was filed as WSR _;</li> <li>✓ Proposal is exempt under RCW 34.05.310(4).</li> </ul>	or Supplemental Notice to WSR  Continuance of WSR
Title of rule and other identifying information: (Describe Subject) WAC 246-310-010 and 280, Certificate of Need definitions and ki	
Hearing location(s): Department of Health Point Plaza East Room 326 310 Israel Road SE Tumwater, WA 98501	Submit written comments to: Name: Yvette Fox Address: Post Office Box 47852 Olympia, WA 98504-7852 Website: http://www3.doh.wa.gov/policyreview/ fax (360) 236-2928 by (date) 10/09/2606
Date: October 26, 2006 Time: 1:30 P.M.	Assistance for persons with disabilities: Contact
Date of intended adoption: 3//35/	Yvette Fox by 10/03/2006
(Note: This is NOT the effective date)  Purpose of the proposal and its anticipated effects, including an	TTY (800) 833-6388 or () 711
to provide these services. The proposed rules ensure clear, timel  Reasons supporting proposal:  The program is authorized in RCW 70.38, Health Planning and D specific types of health services. Rulemaking assures applicants advance to the applicants.  Statutory authority for adoption:	Development, and is responsible for reviewing proposals to provide and affected parties that decision-making is clearly delineated in
RCW 70.38.135	RCW 70.38.135
Is rule necessary because of a:  Federal Law?  Federal Court Decision?  State Court Decision?  If yes, CITATION:  Yes No Yes No Yes No	CODE REVISER USE ONLY
DATE 9/19/06 NAME (type or print)	SEP 2 0 2006
SIGNATURE MC Delich	0.53
TITLE Secretary	06.19.108

Agency comments or recommendations, if a matters:  None	nny, as to statutory language, implementation, enfor	cement, and fiscal
·		
Name of proponent: (person or organization)	Department of Health	Private
		Public Governmental
Name of agency personnel responsible for:		
Name	Office Location	Phone
Drafting Bart Eggen	310 Israel Road SE, Tumwater, Washington 98501	(360) 236-2960
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Has a small business economic impact state	ment been prepared under chapter 19.85 RCW?	
Yes. Attach copy of small business econo	omic impact statement.	
A copy of the statement may be obta	ined by contacting:	
Name: Address:	, `	
phone fax		
e-mail		
<u> </u>		
No. Explain why no statement was prepa A small business economic impact statement is no costs on businesses in an industry.	red. ot required under 19.85.030 (1)(a) RCW. The rule does not in	npose more than minor
No.		
ls a cost-benefit analysis required under RCV	V 34.05.328?	
Yes A preliminary cost-benefit analysis Name: Yvette Fox	may be obtained by contacting:	
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☐ No: Please explain:		
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AMENDATORY SECTION (Amending WSR 04-17-054, filed 8/10/04, effective 9/10/04)

- WAC 246-310-010 Definitions. For the purposes of chapter 246-310 WAC, the following words and phrases ((shall)) have the following meanings unless the context clearly indicates otherwise.
- <u>(1)</u> "Acute care facilities" means hospitals and ambulatory surgical facilities.
- (2) "Affected person" means an interested person ((meeting the following criteria)) who:
- ((ullet)) <u>(a)</u> Is located or resides in the applicant's health service area;
- ((ullet)) (b) Testified at a public hearing or submitted written evidence; and
- $((\bullet))$  (c) Requested in writing to be informed of the department's decision.
- (3) "Alterations," see "construction, renovation, or alteration."
- (4) "Ambulatory care facility" means any place, building, institution, or distinct part thereof not a health care facility as defined in this section and operated for the purpose of providing health services to individuals without providing such services with board and room on a continuous twenty-four-hour basis. The term "ambulatory care facility" includes the offices of private physicians, whether for individual or group practice.
- (5) "Ambulatory surgical facility" means any free-standing entity, including an ambulatory surgery center((7)) that operates primarily for the purpose of performing surgical procedures to treat patients not requiring hospitalization. This term does not include a facility in the offices of private physicians or dentists, whether for individual or group practice, if the privilege of using ((such)) the facility is not extended to physicians or dentists outside the individual or group practice.
  - (6) "Applicant," means:
- (( $\bullet$ )) <u>(a)</u> Any person proposing to engage in any undertaking subject to review under ((the provisions of)) chapter 70.38 RCW(( $\cdot$ )); or
- ((♠)) (b) Any person or individual with a ten percent or greater financial interest in a partnership or corporation or other comparable legal entity engaging in any undertaking subject to review under ((the provisions of)) chapter 70.38 RCW.
- (("Base year" as used in the kidney dialysis station methodology means the last full calendar year preceding the first year of dialysis station need projections.))
- (7) "Bed banking" means the process of retaining the rights to nursing home bed allocations which are not licensed as outlined in WAC 246-310-395.

- (8) "Bed supply" means within a geographic area the total number of:
- ((♠)) (a) Nursing home beds which are licensed or certificate of need approved but not yet licensed or beds banked under ((the provisions of)) RCW 70.38.111 (8)(a) or where the need is deemed met under ((the provisions of)) RCW 70.38.115 (13)(b), excluding:
- ((•)) (i) Those nursing home beds certified as intermediate care facility for the mentally retarded (ICF-MR) the operators of which have not signed an agreement on or before July 1, 1990, with the department of social and health services department of social and health services to give appropriate notice prior to termination of the ICF-MR service;
- ((♠)) (ii) New or existing nursing home beds within a CCRC which are approved under ((the provisions of)) WAC 246-310-380(5); or
- ((\*)) (iii) Nursing home beds within a CCRC which is excluded from the definition of a health care facility per RCW 70.38.025(6); and
- ((♠)) (iv) Beds banked under ((the provisions of)) RCW 70.38.115 (13)(b) where the need is not deemed met.
- ((•)) (b) Licensed hospital beds used for long-term care or certificate of need approved hospital beds to be used for long-term care not yet in use, excluding swing-beds.
- (9) "Bed-to-population ratio" means the nursing home bed supply per one thousand persons of the estimated or forecasted resident population age sixty-five and older.
- (10) "Capital expenditure": Except for WAC 246-310-280, capital expenditure means an expenditure, including a force account expenditure (i.e., an expenditure for a construction project undertaken by a nursing home facility as its own contractor), which, under generally accepted accounting principles, is not properly chargeable as an expense of operation or maintenance. costs of any studies, surveys, designs, plans, working drawings, specifications, and other activities (including staff effort, consulting and other services which, under generally accepted accounting principles, are not properly chargeable as an expense of operation and maintenance) shall be considered capital Where a person makes an acquisition under lease or expenditures. comparable arrangement, or through donation, which would have required certificate of need review if the acquisition had been made by purchase, ((such)) this acquisition shall be deemed a capital expenditure. Capital expenditures include donations of equipment or facilities to a nursing home facility, which if acquired directly by ((such)) the facility, would be subject to review under ((the provisions of)) this chapter and transfer of equipment or facilities for less than fair market value if a transfer of the equipment or facilities at fair market value would be subject to ((such)) the review.
- (11) "Certificate of need" means a written authorization by the secretary's designee for a person to implement a proposal for one or more undertakings.
- (12) "Certificate of need program" means that organizational program of the department responsible for the management of the

certificate of need program.

- (13) "Commencement of the project" means whichever of the following occurs first: In the case of a construction project, giving notice to proceed with construction to a contractor for a construction project provided applicable permits have been applied for or obtained within sixty days of ((such)) the notice; beginning site preparation or development; excavating or starting the foundation for a construction project; or beginning alterations, modification, improvement, extension, or expansion of an existing building. In the case of other projects, initiating a health service.
- (14) "Construction, renovation, or alteration" means the erection, building, remodeling, modernization, improvement, extension, or expansion of a physical plant of a health care facility, or the conversion of a building or portion thereof to a health care facility.
- (15) "Continuing care contract" means a contract providing a person, for the duration of that person's life or for a term in excess of one year, shelter along with nursing, medical, health-related, or personal care services. The contract is conditioned on the transfer of property, the payment of an entrance fee to the provider of ((such)) the services, or the payment of periodic charges for the care and services involved. A continuing care contract is not excluded from this definition because the contract is mutually terminable or because shelter and services are not provided at the same location.
- (16) "Continuing care retirement community (CCRC)" means any of a variety of entities, unless excluded from the definition of health care facility under RCW 70.38.025(6), which provides shelter and services based on continuing care contracts with its residents which:
- ((♠)) Maintains for a period in excess of one year a CCRC contract with a resident which provides or arranges for at least the following specific services:
  - ((♠)) (a) Independent living units;
- ((•)) (b) Nursing home care with no limit on the number of medically needed days;
  - ((\*)) (c) Assistance with activities of daily living;
- ((♠)) (d) Services equivalent in scope to either state chore services or Medicaid home health services;
- ((ullet)) <u>(e)</u> Continues a contract, if a resident is no longer able to pay for services;
- ((♠)) (f) Offers services only to contractual residents with limited exception during a transition period; and
- ((ullet)) (g) Holds the Medicaid program harmless from liability for costs of care, even if the resident depletes his or her personal resources.
- (17) "Days" means calendar days. Days are counted starting the day after the date of the event from which the designated period of time begins to run. If the last day of the period falls on a Saturday, Sunday, or legal holiday observed by the state of Washington, a designated period runs until the end of the first working day following the Saturday, Sunday, or legal holiday.

- (18) "Department" means the Washington state department of health.
  - (19) "Effective date of facility closure" means:
- $((\bullet))$  The date on which the facility's license was relinquished, revoked or expired; or
- ((•)) (b) The date the last resident leaves the facility, whichever comes first.
- (("End-of-the-year incenter patients" means the number of patients receiving incenter kidney dialysis at the end of the calendar year.

"End-stage renal dialysis (ESRD) service areas" means each individual county, designated by the department as the smallest geographic area for which kidney dialysis station need projections are calculated, or other service area documented by patient origin.))

- (20) "Enhance the quality of life for residents" means, for the purposes of voluntary bed banking, those services or facility modifications which have a direct and immediate benefit to the residents. These ((shall)) include, but are not ((be)) limited to: Resident activity and therapy facilities; family visiting rooms; spiritual rooms and dining areas. These services or facility modifications shall not include those that do not have direct and immediate benefit to the residents, such as: Modifications to staff offices; meeting rooms; and other staff facilities.
- (21) "Established ratio" means a bed-to-population ratio of forty beds per one thousand persons of the estimated or forecast resident population age sixty-five and older established for planning and policy-making purposes. The department may revise this established ratio using the process outlined in WAC 246-310-370.
- (22) "Estimated bed need" means the number of nursing home beds calculated by multiplying the planning area's forecasted resident population by the established ratio for the projection year.
- (23) "Estimated bed projection" means the number of nursing home beds calculated by the department statewide or within a planning area, by the end of the projection period.
- (24) "Ex parte contact" means any oral or written communication between any person in the certificate of need program or any other person involved in the decision regarding an application for, or the withdrawal of, a certificate of need and the applicant for, or holder of, a certificate of need, any person acting on behalf of the applicant or holder, or any person with an interest regarding issuance or withdrawal of a certificate of need.
- (25) "Expenditure minimum" means one million dollars for the twelve-month period beginning with July 24, 1983, adjusted annually by the department according to ((the provisions of)) WAC 246-310-900.
- (26) "Health care facility" means hospitals, psychiatric hospitals, nursing homes, kidney disease treatment centers including freestanding dialysis units, ambulatory surgical facilities, continuing care retirement communities, hospices and home health agencies, and includes ((such)) the facilities when

owned and operated by a political subdivision or instrumentality of the state and ((such)) other facilities as required by federal law and ((implementing regulations)) rules, but does not include any health facility or institution conducted by and for those who rely exclusively upon treatment by prayer or spiritual means in accordance with the creed or tenets of any well-recognized church or religious denomination, or any health facility or institution operated for the exclusive care of members of a convent as defined in RCW 84.36.800 or rectory, monastery, or other institution operated for the care of members of the clergy.

- (a) In addition, the term "health care facility" does not include any nonprofit hospital:
- ((ullet)) (i) Operated exclusively to provide health care services for children;
- ((ullet)) (ii) Which does not charge fees for  $(({\color{red} {\rm such}}))$  the services; and
- $((\bullet))$  (iii) If not contrary to federal law as necessary to the receipt of federal funds by the state.
- ((♠)) (b) In addition, the term "health care facility" does not include a continuing care retirement community which:
  - ((♠)) (i) Offers services only to contractual residents;
- ((♠)) (ii) Provides its residents a contractually guaranteed range of services from independent living through skilled nursing, including some form of assistance with activities of daily living;
- ((•)) (iii) Contractually assumes responsibility for costs of services exceeding the resident's financial responsibility as stated in contract, so that, with the exception of insurance purchased by the retirement community or its residents, no third party, including the Medicaid program, is liable for costs of care even if the resident depletes personal resources;
- ((•)) (iv) Offers continuing care contracts and operates a nursing home continuously since January 1, 1988, or obtained a certificate of need to establish a nursing home;
- ((\*)) <u>(v)</u> Maintains a binding agreement with the department of social and health services assuring financial liability for services to residents, including nursing home services, shall not fall upon the department of social and health services;
- ((\*)) (vi) Does not operate, and has not undertaken, a project resulting in a number of nursing home beds in excess of one for every four living units operated by the continuing care retirement community, exclusive of nursing home beds; and
- ((•)) (vii) Has undertaken no increase in the total number of nursing home beds after January 1, 1988, unless a professional review of pricing and long-term solvency was obtained by the retirement community within the prior five years and fully disclosed to residents.
- (27) "Health maintenance organization" means a public or private organization, organized under the laws of the state, which:
- ((♦)) (a) Is a qualified health maintenance organization under Title XIII, Section 1310(d) of the Public Health Service Act; or
- ((•)) (b) Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: Usual physician services,

hospitalization, laboratory, X ray, emergency and preventive services, and out-of-area coverage;

- ((\*)) (c) Is compensated (except for copayments) for the provision of the basic health care services listed in this subsection to enrolled participants by a payment made on a periodic basis without regard to the date the health care services are provided and fixed without regard to the frequency, extent, or kind of health service actually provided; and
  - ((•)) (d) Provides physicians' services primarily:
- $((\bullet))$  <u>(i)</u> Directly through physicians who are either employees or partners of ((such)) <u>the</u> organization((7)); or
- ((ullet)) (ii) Through arrangements with individual physicians or one or more groups of physicians (organized on a group practice or individual practice basis).
- (28) "Health service area" means a geographic region appropriate for effective health planning including a broad range of health services.
- (29) "Health services" means clinically related (i.e., preventive, diagnostic, curative, rehabilitative, or palliative) services and includes alcoholism, drug abuse, and mental health services.
- (30) "Home health agency" means an entity which is, or has declared ((an)) its intent to become, certified as a provider of home health services in the Medicaid or Medicare program.
- (31) "Hospice" means an entity which is, or has declared ((an)) its intent to become, certified as a provider of hospice services in the Medicaid or Medicare program.
- (32) "Hospital" means any institution, place, building or agency or distinct part thereof which qualifies or is required to qualify for a license under chapter 70.41 RCW, or as a psychiatric hospital licensed under chapter 71.12 RCW.
- (33) "Inpatient" means a person receiving health care services with board and room in a health care facility on a continuous twenty-four-hour-a-day basis.
  - (34) "Interested persons" means:
  - ((♠)) <u>(a)</u> The applicant;
- ((\*)) (b) Health care facilities and health maintenance organizations providing services similar to the services under review and located in the health service area;
- ((ullet)) <u>(c)</u> Third-party payers reimbursing health care facilities in the health service area;
- ((\*)) (d) Any agency establishing rates for health care facilities and health maintenance organizations in the health service area where the proposed project is to be located;
- ((♠)) (e) Health care facilities and health maintenance organizations which, in the twelve months prior to receipt of the application, have submitted a letter of intent to provide similar services in the same planning area;
- ((ullet)) (f) Any person residing within the geographic area to be served by the applicant; and
- $((\bullet))$  (g) Any person regularly using health care facilities within the geographic area to be served by the applicant.
  - (("Justified home training station" means a kidney dialysis

station designated for home hemodialysis and/or peritoneal dialysis training. When no dialysis stations have been designated for home training at a given dialysis treatment center, one station for every six patients trained for home hemodialysis, and one station for every twenty patients for peritoneal dialysis, will be considered a justified home training station. In no case shall all stations at a given dialysis treatment center be designated as justified home training stations. To request justified home training stations at a new dialysis treatment center, the applicant must document that at least six patients are projected to be trained for home hemodialysis or twenty patients for peritoneal dialysis for each such station requested for each of the first five years of projected operations.

"Kidney disease treatment center" means any place, institution, building or agency or a distinct part thereof equipped and operated to provide services, including outpatient dialysis and/or kidney transplantation, to persons who have end-stage renal disease (ESRD).)

- (35) "Licensee" means an entity or individual licensed by the department of health or the department of social and health services. For the purposes of nursing home projects, licensee refers to the operating entity and those persons specifically named in the license application as defined under chapter 388-97 WAC.
- (36) "Net estimated bed need" means estimated bed need of a planning area changed by any redistribution as follows:
- ((ullet)) (a) Adding nursing home beds being redistributed from another nursing home planning area or areas; or
- ((♠)) (b) Subtracting nursing home beds being redistributed to another nursing home planning area or areas.
- (37) "New nursing home bed" means a nursing home bed never licensed by the state or beds banked under ((the provisions of)) RCW 70.38.115(13), where the applicant must demonstrate need for the previously licensed nursing home beds. This term does not include beds banked under ((the provisions of)) RCW 70.38.111(8).
- (38) "Nursing home" means any entity licensed or required to be licensed under ((the provisions of)) chapter 18.51 RCW or distinct part long-term care units located in a hospital and licensed under chapter 70.41 RCW.
- (39) "Obligation," when used in relation to a capital expenditure, means the following has been incurred by or on behalf of a health care facility:
- ((♠)) (a) An enforceable contract has been entered into by a health care facility or by a person on behalf of the health care facility for the construction, acquisition, lease, or financing of a capital asset; or
- ((lacktriangle)) A formal internal commitment of funds by a health care facility for a force account expenditure constituting a capital expenditure; or
- $((\bullet))$  <u>(c)</u> In the case of donated property, the date on which the gift is completed in accordance with state law.
- (40) "Offer," when used in connection with health services, means the health facility provides one or more specific health services.

- (41) "Over the established ratio" means the bed-to-population ratio is greater than the statewide current established ratio.
- (42) "Person" means an individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies, and insurance companies), the state, or a political subdivision or instrumentality of the state, including a municipal corporation or a hospital district.
- (43) "Planning area" means each individual county designated by the department as the smallest geographic area for which nursing home bed need projections are developed, except as follows:
- ((ullet)) (a) Clark and Skamania counties shall be one planning area.
- ((ullet)) (b) Chelan and Douglas counties shall be one planning area.
- (44) "Predevelopment expenditures" means capital expenditures, the total of which exceeds the expenditure minimum, made for architectural designs, plans, drawings, or specifications in preparation for the acquisition or construction of physical plant facilities. "Predevelopment expenditures" exclude any obligation of a capital expenditure for the acquisition or construction of physical plant facilities and any activity which the department may consider the "commencement of the project" as this term is defined in this section.
- (45) "Professional review of continuing care retirement community pricing and long-term solvency" means prospective financial statements, supported by professional analysis and documentation, which:
- ((♠)) (a) Conform to Principles and Practices Board Statement Number 9 of the Healthcare Financial Management Association, "Accounting and Reporting Issues Related to Continuing Care Retirement Communities"; and
- ((ullet)) <u>(b)</u> Project the financial operations of the continuing care retirement community over a period of ten years or more into the future; and
- ((•)) (c) Are prepared and signed by a qualified actuary as defined under WAC 284-05-060 or an independent certified public accountant, or are prepared by management of the continuing care retirement community and reviewed by a qualified actuary or independent certified public accountant who issues a signed examination or compilation report on the prospective financial statements; and
- ((ullet))  $\underline{(d)}$  Include a finding by management that the intended expansion project of the continuing care retirement project is financially feasible.
- (46) "Project" means all undertakings proposed in a single certificate of need application or for which a single certificate of need is issued.
- (47) "Project completion" for projects requiring construction, means the date the facility is licensed. For projects not requiring construction, project completion means initiating the health service.
- (48) "Projection period" means the three-year time interval following the projection year.

- (49) "Projection year" for nursing home purposes, means the one-year time interval preceding the projection period. ((For kidney dialysis station projection purposes, means the base year plus three years.))
- (50) "Public comment period" means the time interval during which the department shall accept comments regarding a certificate of need application.
- (51) "Redistribution" means the shift of nursing home bed allocations between two or more planning areas or the shift of nursing home beds between two or more nursing homes.
- (52) "Replacement authorization" means a written authorization by the secretary's designee for a person to implement a proposal to replace existing nursing home beds in accordance with the eligibility requirements in WAC 246-310-044 and notice requirements in WAC 246-310-396.
- (53) "Resident population" for purposes of nursing home projects, means the number of residents sixty-five years of age and older living within the same geographic area which:
- ((ullet)) (a) Excludes contract holders living within a recognized CCRC:
- $((\bullet))$  <u>(i)</u> With approval for new nursing home beds under ((the provisions of)) WAC 246-310-380(((the provisions of))) WAC 246-310-380(((the provisions of))) WAC 246-310-380(((the provisions of)))
- $((\bullet))$  (ii) Excluded from the definition of a health care facility per RCW 70.38.025(6);
  - ((♠)) (b) Is calculated using demographic data obtained from:
  - ((♠)) (i) The office of financial management; and
- $((\bullet))$  (ii) Certificate of need applications and exemption requests previously submitted by a CCRC.
- (54) "Secretary" means the secretary of the Washington state department of health or the secretary's designee.
- (55) "State Health Planning and Resources Development Act" means chapter 70.38 RCW.
- (56) "Statewide current ratio" means a bed-to-population ratio computed from the most recent statewide nursing home bed supply and the most recent estimate of the statewide resident population.
- (57) "Swing beds" means up to the first five hospital beds designated by an eligible rural hospital which are available to provide either acute care or nursing home services.
- (58) "Tertiary health service" means a specialized service meeting complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care.
- (59) "Transition period" means the period of time, not exceeding five years, between the date a CCRC is inhabited by a member, and the date it fully meets the requirements of a CCRC.
- (60) "Under the established ratio" means the bed-to-population ratio is less than the statewide current established ratio.
- (61) "Undertaking" means any action subject to the provisions of chapter 246-310 WAC.
- (62) "Working days" excludes Saturdays, Sundays, and legal holidays observed by the state of Washington. Working days are counted in the same way as calendar days.

- WAC 246-310-280 Kidney disease treatment centers—Definitions. (((1) To receive approval, a kidney disease treatment center providing hemo or peritoneal dialysis, training, or backup must meet the following standards in addition to applicable review criteria in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240.
- (2) The number of dialysis stations needed in an ESRD service area shall be determined using the following data of the Northwest Renal Network:
- (a) The ESRD service area's total number of in center dialyses provided for the previous five years.
- (b) The number of end of year incenter patients for the ESRD service area for the previous five years.
- (c) The number of patients trained for home hemo and peritoneal dialysis for the ESRD service area for the previous five years.
- (3) The number of dialysis stations projected as needed in an ESRD service area shall be determined using the following methodology:
- (a) Project the number of incenter dialyses needed in the ESRD service area through a three-year future regression analysis of the previous five years' data.
- (b) Project the number of incenter dialyses needed to serve residents of the ESRD service area by projecting the number of end of year incenter patients through a three-year future regression analysis of patient origin adjusted data for the previous five years. Multiply this result by one hundred fifty-six dialyses per year.
- (c) Project the number of patients to be trained for home hemo and peritoneal dialysis in the service area through a three-year regression analysis of the previous five years' data.
- (d) Determine the number of dialysis stations needed for incenter dialysis by dividing the result of (a) of this subsection by 748.8 (equivalent to eighty percent of a three-patient shift schedule).
- (e) Determine the number of dialysis stations needed for incenter dialysis to serve residents of the service area by dividing the result of (b) of this subsection by 748.8 (equivalent to eighty percent of a three-patient shift schedule).
- (f) Determine the number of stations needed for home hemo and peritoneal training in the service area by dividing the projected number of home hemo patients to be trained by six and peritoneal patients to be trained by twenty.
- (g) Determine the number of dialysis stations needed in a service area by the projection year as the total of:
- (i) The result of (e) of this subsection, designated as the number of resident stations;
- (ii) The result of (d) of this subsection, minus the result of (e) of this subsection, designated as visitor stations;

- (iii) The result of (f) of this subsection, designated as the number of training stations.
- (h) To determine the net station need for an ESRD service area, subtract the number calculated in (g) of this subsection from the total number of certificate of need approved stations.
- (4) All kidney disease treatment centers that would stand to lose market share by approval of the applicant's facility, must be operating at 748.8 dialyses per nontraining station per year before additional nontraining stations are approved.
- (5) New incenter kidney disease treatment stations must reasonably project to be operating at 748.8 dialyses per nontraining station per year by the third year of operation.
- (6) The department shall not issue certificates of need approving more than the number of stations identified as being needed in a given ESRD service area unless:
- (a) The department finds such additional stations are needed to be located reasonably close to the people they serve; or
- (b) Existing nontraining dialysis stations in the treatment facility are operating at nine hundred thirty-six dialyses per year (three-patient shifts); or
- (c) The applicant can document a significant change in ESRD treatment practice has occurred, affecting dialysis station utilization in the service area, and

The department finds that an exceptional need exists and explains such approval in writing.)) The following definitions apply to WAC 246-310-280, 246-310-282, 246-310-284, 246-310-286, 246-310-287, 246-310-288, and 246-310-289:

- (1) "Base year" means the most recent calendar year for which December 31 data is available from the Northwest Renal Network's Modality Report.
- (2) "Capital expenditures," as defined by Generally Accepted Accounting Principles (GAAP), are expenditures made to acquire tangible long-lived assets. Long-lived assets represent property and equipment used in a company's operations that have an estimated useful life greater than one year. Acquired long-lived assets are recorded at acquisition cost and include all costs incurred necessary to bring the asset to working order. The definition of a capital expenditure includes the following types of expenditures or acquisitions:
- (a) A force account expenditure or acquisition (i.e., an expenditure for a construction project undertaken by a facility as its own contractor).
- (b) The costs of any site planning services (architect or other site planning consultant) including but not limited to studies, surveys, designs, plans, working drawings, specifications, and other activities (including applicant staff payroll and employee benefit costs, consulting and other services which, under GAAP or Financial Accounting Standards Board (FASB) may be chargeable as an operating or nonoperating expense).
- (c) Capital expenditure or acquisition under an operating or financing lease or comparable arrangement, or through donation, which would have required certificate of need review if the capital

expenditure or acquisition had been made by purchase.

- (d) Building owner tenant improvements including but not limited to: Asbestos removal, paving, concrete, contractor's general conditions, contractor's overhead and profit, electrical, heating, ventilation and air conditioning systems (HVAC), plumbing, flooring, rough and finish carpentry and millwork and associated labor and materials, and utility fees.
- (e) Capital expenditures include donations of equipment or facilities to a facility.
- (f) Capital expenditures do not include routine repairs and maintenance costs that do not add to the utility of useful life of the asset.
- (3) "Concurrent review" means the process by which applications competing to provide services in the same planning area are reviewed simultaneously by the department. The department compares the applications to one another and these rules.
- (4) "End-of-year data" means data contained in the fourth quarter modality report from the Northwest Renal Network. For these rules, end-of-year and year-end have the same meaning.
- (5) "End-of-year in-center patients" means the number of resident in-center hemodialysis (HD) patients receiving in-center kidney dialysis at the end of the calendar year based on end-of-year data.
- (6) "Kidney disease treatment center" means any place, institution, building or agency or a distinct part thereof equipped and operated to provide services, including outpatient dialysis, to persons who have end-stage renal disease (ESRD). In no case shall all stations at a given kidney disease treatment center be designated as home training stations. For purposes of these rules, kidney disease treatment center and kidney dialysis facility have the same meaning.
- (7) "Kidney dialysis facility" means any place, institution, building or agency or a distinct part thereof equipped and operated to provide services, including outpatient dialysis, to persons who have end-stage renal disease (ESRD). In no case shall all stations at a given kidney dialysis facility be designated as home training stations. For purposes of these rules, kidney dialysis facility and kidney disease treatment center have the same meaning.
- (8) "Planning area" means an individual geographic area designated by the department for which kidney dialysis station need projections are calculated. For purposes of kidney dialysis projects, planning area and service area have the same meaning.
- (9) "Planning area boundaries": Each county is a separate planning area, except for the planning subareas identified for King, Snohomish, Pierce, and Spokane counties. If the United States Postal Service (USPS) changes zip codes in the defined planning areas, the department will update areas to reflect the revisions to the zip codes to be included in the certificate of need definitions, analyses and decisions.
- (a) King County is divided by zip code into twelve planning areas as follows:

KING ONE	KING TWO	KING THREE
98028 Kenmore	98101 Business <u>District</u>	98013 Vashon
98103 Green Lake	98102 Eastlake	98070 Vashon
98105 Laurelhurst	98104 Business District	98106 White Center/West Seattle
98107 Ballard	98108 Georgetown	98116 Alki/West Seattle
98115 View Ridge/Wedgwood	98109 Queen Anne	98126 West Seattle
98117 Crown Hill	98111 Rainier Beach	98136 West Seattle
98125 Lake City	98112 Madison/Capitol Hill	98146 West Scattle
98133 Northgate	98118 Columbia City	98168 Riverton
98145 University of Washington	98119 Queen Anne	
98155 Shoreline/Lake Forest Park	98121 Denny Regrade	
98177 Richmond Beach	98122 Madrona	
98195 University of Washington	98134 Harbour Island	
	98144 Mt. Baker/Rainier Valley	
	98199 Magnolia	

KING FOUR	KING FIVE	KING SIX
98054 Redondo	98003 Federal Way	98011 Bothell
98062 Seahurst	98023 Federal Way	98012 Mill Creek
98148 SeaTac	98063 Federal Way	98021 Bothell
98158 SeaTac		98033 Kirkland
98166 Burien/Normandy Park		98034 Kirkland
98188 Tukwila/SeaTac		98052 Redmond
98198 Des Moines		98053 Redmond
		98072 Woodinville
		98077 Woodinville

KING SEVEN	KING EIGHT	KING NINE
98004 Bellevue	98014 Carnation	98055 Renton
98005 Bellevue	98019 Duvall	98056 Renton
98006 Bellevue	98024 Fall City	98057 Renton
98007 Bellevue	98025 Hobart	98058 Renton
98008 Bellevue	98045 North Bend	98059 Renton
98009 Bellevue	98050 Preston	98178 Skyway
98015 Bellevue		
98027 Issaguah	98068 Hyak/Snoqualmic Pass	
98029 Issaquah	98065 Snoqualmie	
98039 Medina		
98040 Mercer Island		
98074 Sammamish		
98075 Sammamish		

KING TEN	KING ELEVEN	KING TWELVE
98030 Kent	<u>98001 Auburn</u>	98022 Enumelaw

KING TEN	KING ELEVEN	KING TWELVE
98031 Kent	98002 Auburn	98035 Lester
98032 Kent	98010 Black Diamond	
98038 Maple Valley	98047 Pacific	
98042 Kent	98071 Auburn	
98051 Ravensdale	98091 Auburn	
98064 Kent	98092 Auburn	

## (b) Pierce County is divided into five planning areas as follows:

PIERCE ONE	PIERCE TWO	PIERCE THREE
98348 La Grande	98304 Ashford	98329 Gig Harbor
98352 Sumner	98323 Carbonade	98332 Gig Harbor
98354 Milton	98328 Eatonville	98333 Fox Island
98371 Puyallup	98330 Elbe	98335 Gig Harbor
98372 Puyallup	98360 Orting	98349 Lakebay
98373 Puyallup	98338 Graham	98351 Longbranch
98374 Puyallup	98321 Buckley	98394 Vaughn
98375 Puyallup		98395 Wauna
98385 South Prairie		
<u>98390 Summer</u>		
98396 Wilkeson		
98397 Longmire		

PIERCE FOUR	PIERCE FIVE
98402 Tacoma	98303 Anderson Island
98403 Tacoma	98327 DuPont
<u>98404 Tacoma</u>	98387 Spanaway
98405 Tacoma	98388 Steilacoom
98406 Tacoma	98430 Tacoma
98407 Ruston	98431 Tacoma
98408 Tacoma	98433 Tacoma
98409 Lakewood	98438 Tacoma
98411 Tacoma	98439 Lakewood
98413 Tacoma	98442 Tacoma
98416 Tacoma	98444 Parkland
98418 Tacoma	98445 Parkland
98421 Tacoma	98446 Parkland
98422 Tacoma	98447 Tacoma
98424 Fife	98467 University Place
98443 Tacoma	98492 Lakewood
98450 Tacoma	98493 Tacoma
98455 Tacoma	98497 Lakewood
98460 Tacoma	98498 Lakewood
98464 University Place	98499 Lakewood
98465 Tacoma	98558 McKenna
98466 Fircrest	98580 Roy

## (c) Snohomish County is divided into three planning areas as follows:

SNOHOMISH	<u>SNOHOMISH</u>	SNOHOMISH
ONE	<u>TWO</u>	THREE
98223 Arlington	98201 Everett	98012 Mill Creek/Bothell

SNOHOMISH ONE	SNOHOMISH • TWO	SNOHOMISH THREE
98241 Darrington	98203 Everett	98020 Edmonds/Woodway
98252 Granite Falls	98204 Everett	98021 Bothell
98259 North Lakewood	98205 Everett	98026 Edmonds
98271 Tulalip Reservation/ Marysville	98208 Everett	98036 Lynnwood/Brier
98282 Camano Island	98251 Gold Bar	98037 Lynnwood
98287 Silvana	98256 Index	98043 Mountlake Terrace
	98224 Baring	
98292 Stanwood	98258 Lake Stevens	98087 Lynnwood
	98270 Marysville	98296 Snohomish
	98272 Monroe	
	98275 Mukilteo	
	98288 Skykomish	
	98290 Snohomish	
	98293 Startup	
	98294 Sultan	

(d) Spokane County is divided into two planning areas as follows:

SPOKANE ONE	SPOKANE TWO
99001 Airway Heights	99003 Chattaroy
99004 Cheney	99005 Colbert
99011 Fairchild Air Force Base	99006 Deer Park
99012 Fairfield	99009 Elk
99014 Four Lakes	99021 Mead
99016 Greenacres	99025 Newman Lake
99018 Latah	99027 Otis Orchards
99019 Liberty Lake	99205 Spokane
99020 Marshall	99207 Spokane
99022 Medical Lake	99208 Spokane
99023 Mica	99209 Spokane
99030 Rockford	99217 Spokane
99031 Spangle	99218 Spokane
99036 Valleyford	99228 Spokane
99037 Veradale	99251 Spokane
99039 Waverly	99252 Spokane
99201 Spokane	
99202 Spokane	
99203 Spokane	
99204 Spokane	
99206 Spokane Valley	
99210 Spokane	
99211 Spokane Valley	
99212 Spokane Valley	
99213 Spokane Valley	
99214 Spokane Valley	
99215 Spokane/Spokane Valley	
99216 Spokane/Spokane Valley	
99219 Spokane/Sunset Hill	

SPOKANE ONE	SPOKANE TWO
99220 Spokane	
99223 Spokane	
99224 Spokane	
99256 Spokane	
99258 Spokane	
99260 Spokane	
99299 Spokane	

- (10) "Projection year" means the fourth year after the base year. For example, reviews using 2005 year-end data as the base year will use 2009 as the projection year.
- (11) "Resident in-center patients" means hemodialysis (HD) patients that reside within the planning area. If more than fifty percent of a facility's patients reside outside Washington state, the facility may include these out-of-state patients in the resident count for the planning area.
- (12) "Service area" means an individual geographic area designated by the department for which kidney dialysis station need projections are calculated. For purposes of kidney dialysis projects, service area and planning area have the same meaning.
- (13) "Training services" means services provided by a kidney dialysis facility to train patients for home dialysis. Types of home dialysis include at least, but are not limited to, the following:
  - (a) Home peritoneal dialysis; and
  - (b) Home hemodialysis (HHD).

#### NEW SECTION

WAC 246-310-282 Kidney disease treatment centers--Concurrent review cycle. The department will review kidney dialysis facility applications using the concurrent review cycle described in this section. There are four concurrent review cycles each year; a cycle begins in January, April, July and October.

(1) Applicants must submit applications for review according to the following table:

		Application Submission Period			Department Action	Application Review Period		
Concurrent Review Cycle	Letters of Intent Due	Receipt of Initial Application	End of Screening Period	Applicant Response	Beginning of     Review     Preparation	Public Comment Period (includes public hearing if requested)	Rebuttal Period	Exparte Period
Kidney Dialysis Facility Cycle 1	First working day and last working day of January of each year.	First working day and last working day of February of each year.	Last working day of March of each year.	Last working day of April of each year.	May 1 through May 15	60-Day Public comment period  Begins May 16 of each year or the first working day after May 16.	30-Day Rebuttal period  Applicant and affected party response to public comment.	45-Day Exparte period  Department evaluation and decision.
Kidney Dialysis Facility Cycle 2	First working day and last working day of April of each year.	First working day and last working day of <b>May</b> of each year.	Last working day of <b>June</b> of each year.	Last working day of July of each year.	August I through August 15	60-Day Public comment period  Begins August 16 of each year or the first working day after August 16.	30-Day Rebuttal period  Applicant and affected party response to public comment.	45-Day Exparte period  Department evaluation and decision.
Kidney Dialysis Facility Cycle 3	First working day and last working day of July of each year.	First working day and last working day of August of each year.	Last working day of September of each year.	Last working day of October of each year.	November 1 through November 15	60-Day Public comment period  Begins November 16 of each year or the first working day after November 16.	30-Day Rebuttal period  Applicant and affected party response to public comment.	45-Day Exparte period  Department evaluation and decision.
Kidney Dialysis Facility Cycle 4	First working day and last working day of October of each year.	First working day and last working day of November of each year.	Last working day of December of each year.	Last working day of January of each year.	February I through February 15	60-Day Public comment period  Begins February 16 of each year or the first working day after February 16.	30-Day Rebuttal period  Applicant and affected party response to public comment.	45-Day Exparte period Department evaluation and decision.

- (2) The department should complete a concurrent review cycle within nine months. The department should complete the regular review process within six months.
- (3) The department will notify applicants fifteen days prior to the scheduled decision date if it is unable to meet the deadline for making a decision on the application. In that event, the

department will establish and commit to a new decision date.

- (4) The department will not accept new applications for a planning area if there are any pending applications in that planning area filed under a previous concurrent review cycle, unless the department has not made a decision on the pending applications within the review timelines of nine months for a concurrent review and six months for a regular review.
- (5) The department may convert the review of an application that was initially submitted under the concurrent review cycle to a regular review process if the department determines that the application does not compete with another application.

#### NEW SECTION

- WAC 246-310-284 Kidney disease treatment centers-Methodology. A kidney dialysis facility that provides hemodialysis or peritoneal dialysis, training, or backup must meet the following standards in addition to applicable review criteria in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240.
- (1) Applications for new stations may only address projected station need in the planning area in which the facility is to be located.
- (a) If there is no existing facility in an adjacent planning area, the application may also address the projected station need in that planning area.
- (b) Station need projections must be calculated separately for each planning area within the application.
- (2) Data used to project station need must be the most recent five-year resident in-center year-end patient data available from the Northwest Renal Network as of the first day of the application submission period, concluding with the base year at the time of application.
- (3) Projected station need must be based on 4.8 resident incenter patients per station for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties. The projected station need for these exception planning areas must be based on 3.2 resident incenter patients per station.
- (4) The number of dialysis stations projected as needed in a planning area shall be determined by using the following methodology:
- (a) Determine the type of regression analysis to be used to project resident in-center station need by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year.
  - (i) If the planning area has experienced less than six percent

growth in any of the previous five annual changes calculations, use linear regression to project station need; or

- (ii) If the planning area has experienced six percent or greater growth in each of the previous five annual changes, use nonlinear (exponential) regression to project station need.
- (b) Project the number of resident in-center patients in the projection year using the regression type determined in (a) of this subsection. When performing the regression analysis use the previous five consecutive years of year-end data concluding with the base year. For example, if the base year is 2005, use year-end data for 2001 through 2005 to perform the regression analysis.
- (c) Determine the number of dialysis stations needed to serve resident in-center patients in the planning area in the projection year by dividing the result of (b) of this subsection by the appropriate resident in-center patient per station number from subsection (3) of this section. In order to assure access, fractional numbers are rounded up. For example, 5.1 would be rounded to 6. Rounding is only allowed for determining the number of stations needed.
- (d) To determine the net station need for a planning area, subtract the number calculated in (c) of this subsection from the total number of certificate of need approved stations located in the planning area.
- (5) Before the department approves new in-center kidney dialysis stations, all certificate of need approved stations in the planning area must be operating at 4.8 patients per dialysis station for all areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties. For these exception planning areas all certificate of need approved stations in the planning area must be operating at 3.2 in-center patients per station. Both resident and nonresident patients using the dialysis facility are included in this calculation. Data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the first day of the application submission period.
- (6) By the third full year of operation, new in-center kidney dialysis stations must reasonably project to be operating at:
- (a) 4.8 patients per station for those facilities required to operate at 4.8 patients as identified in subsection (5) of this section; or
- (b) 3.2 patients per station for those facilities required to operate at 3.2 patients as identified in subsection (5) of this section.

#### NEW SECTION

WAC 246-310-286 Kidney disease treatment centers--Standards for planning areas without an existing facility. Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum planning areas do not have an existing kidney dialysis facility as of the effective date of these rules. The department will award the first approvable project proposing to establish a facility in one of these planning areas a minimum of four stations. The facility must be projected to operate at 3.2 resident in-center patients per station by the third full year of operation.

#### NEW SECTION

WAC 246-310-287 Kidney disease treatment centers--Exceptions. The department shall not approve new stations in a planning area if the projections in WAC 246-310-284(4) show no net need, and shall not approve more than the number of stations projected as needed unless:

- (1) All other standards have been met; and
- (2) One or more of the following have been met:
- (a) The department finds the additional stations are needed to be located reasonably close to the people they serve; or
- (b) Existing dialysis stations in the dialysis facility are operating at six patients per station; or
- (c) The applicant can document a significant change in ESRD treatment practice has occurred, affecting dialysis station use in the planning area; and
- (3) The department finds that exceptional circumstances exist within the planning area and explains the approval of additional stations in writing.

#### NEW SECTION

WAC 246-310-288 Kidney disease treatment centers--Tie-breakers. If two or more applications meet all applicable review criteria and there is not enough station need projected for all applications to be approved, the department will use tie-breakers to determine which application or applications will be approved. The department will approve the application accumulating the largest number of points. If sufficient additional stations remain after approval of the first application, the department will approve the application accumulating the next largest number of

points, not to exceed the total number of stations projected for a planning area. If the applications remain tied after applying all the tie-breakers, the department will award stations as equally as possible among those applications, without exceeding the total number of stations projected for a planning area.

- (1) The department will award one point per tie-breaker to any applicant that meets a tie-breaker in this subsection.
  - (a) Training services (1 point):
- (i) The applicant is an existing provider in the planning area and either offers training services at the facility proposed to be expanded or offers training services in any of its existing facilities within a thirty-five mile radius of the existing facility; or
- (ii) The applicant is an existing provider in the planning area proposing to establish a new facility either that offers training services at the new facility or offers training services within a thirty-five mile radius of the proposed new facility; or
- (iii) The applicant, not currently located in the planning area, proposes to establish a new facility with training services and demonstrates a historical and current provision of training services at its other facilities; and
- (iv) Northwest Renal Network's most recent quarterly modality reports must document the provision of these training services by the applicant.
- (b) Private room(s) for isolating patients needing dialysis (1 point).
  - (c) Permanent bed stations at the facility (1 point).
- (d) Evening shift (1 point): The applicant currently offers, or as part of its application proposes to offer at the facility a dialysis shift that begins after  $5:00~\rm p.m.$
- (e) Meeting the projected need (1 point): The applications that propose the number of stations that most closely approximates the projected need.
- (2) Only one applicant may be awarded a point for each of the following four tie-breakers:
- (a) **Economies of scale (1 point):** Compared to the other applications, an applicant demonstrates its proposal has the lowest capital expenditure per new station.
  - (b) Historical provider (1 point):
- (i) The applicant was the first to establish a facility within a planning area; and
- (ii) The application to expand the existing facility is being submitted within five years of the opening of its facility; or
- (iii) The application is to build an additional new facility within five years of the opening of its first facility.
- (c) Patient geographical access (1 point): The application proposing to establish a new facility within a planning area that will result in services being offered closer to people in need of them. The department will award the point for the facility located farthest away from existing facilities within the planning area provided:
  - (i) The facility is at least three miles away from the next

closest existing facility in planning areas that qualify for 4.8 patients per station; or

- (ii) The facility is at least eight miles from the next closest existing facility in planning areas that qualify for 3.2 patients per station.
  - (d) Provider choice (1 point):
- (i) The applicant does not currently have a facility located within the planning area;
- (ii) The department will consider a planning area as having one provider when a single provider has multiple facilities in the same planning area;
- (iii) If there are already two unrelated providers located in the same planning area, no point will be awarded.

#### NEW SECTION

WAC 246-310-289 Kidney disease treatment centers--Relocation of facilities. (1) When an entire facility proposes to relocate to another planning area, a new health care facility is considered to be established under WAC 246-310-020(1).

- (2) When an entire facility proposes to relocate within the same planning area, a new health care facility is not considered to be established under WAC 246-310-020(1) if:
  - (a) The existing facility ceases operation;
  - (b) No new stations are added to the replacement facility;
- (c) There is no break in service between the closure of the existing facility and the operation of the replacement facility;
- (d) The existing facility has been in operation for at least five years at its present location; and
- (e) The existing facility has not been purchased, sold or leased within the past five years.
- . (3) When an existing facility proposes to relocate a portion of its stations to either another planning area or within the same planning area, a new health care facility is considered to be established under WAC 246-310-020(1).